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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/634,054	08/08/2000	David A. Newsome, M.D.	P00005US (53783.1P)	4792

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EXAMINER

HAYES, MICHAEL J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 01/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/634,054

Applicant(s)

NEWSOME, M.D., DAVID A.

Examiner

Michael J Hayes

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27-31 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 30,35 and 36 is/are allowed.
- 6) ☒ Claim(s) 27-29,31 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 August 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28, 29, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "soft" in claims 28 and 34 is a relative term which renders the claims indefinite. The term "soft" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The hardness of the lens material has been rendered indefinite with the use of the term "soft."

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27, 28, 29, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over BECK (U. S. Patent No. 6,319,240) in view of Applicant's disclosure. Beck discloses an apparatus for electrophoresis on an eye including an outer concave/convex shell having an electrode, an inner disposable pre-medicated soft lens with a dilator (8:35-41), and a power

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source for the electrode. Beck does not disclose the lens is polyfilcon or that the power source is light-activated. It would have been obvious to one of ordinary skill in the art at the time of the invention to use polyfilcon as a design choice since Applicant has not disclosed that polyfilcon solves a stated problem or is for any particular purpose and it appears that a lens made from another polymer would work equally as well as a pre-medicated reservoir in contact with the eye. Beck does not disclose a light-activated power source; however Applicant discloses that such power sources are well known and commercially available (pg. 7). It would have been obvious to one of ordinary skill in the art at the time of the invention to use a light-activated power source as the power source in the invention of Beck in order to take advantage of well-known benefits of such a power source. The use and interchangeability of various types of power sources would be obvious to the skilled artisan as equivalents.

#### *Allowable Subject Matter*

Claims 30, 35, and 36 are allowed.

#### *Response to Arguments*

Applicant submits that one of ordinary skill in the art would know the difference between a hard and soft contact lens so that Applicant's recitation in claim 28 that "the lens member is soft" is definite. The examiner disagrees because contact lens are produced in a range of hardnesses from the softest to the hardest. Even if one of ordinary skill in the art can distinguish a soft lens from a hard lens, the distinction is only made relatively. Applicant's recitation of soft has no point of reference and Applicant has not submitted any evidence that a soft lens is only

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limited to one hardness range with a hard lens limited to a distinct, though greater, hardness range. Even a hard lens is soft compared to the hardest hard lens. The examiner maintains that one of ordinary skill in the art can not determine Applicant's metes and bounds of claims 28, 29, and 34. In view of Applicant's specification, it cannot be determined what Applicant considers as soft.

Applicant generally argues that the knowledge of commercially-available light-activated power sources is insufficient to suggest using such as a power source to provide electricity for electrophoresis. The examiner does not agree because the use of commercially-available light-activated power sources is well known as recognized by Applicant. Beck discloses the claimed invention including a power source. One of ordinary skill in the art of electrophoresis would know that power can be supplied from a variety of sources to provide an electromotive force for administering drugs, and light-activated power sources are well known to provide such needed electricity. Applicant's arguments that there is no teaching of using a light-activated power source to provide electricity for electrophoresis goes to a method of performing electrophoresis and is not convincing with respect to the pending apparatus claims.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. PAREL et al. (U. S. Patent No. 6,154,671) and ABREU (U. S. Patent No. 6,312,393) show devices for performing electrophoresis on a patient's eye.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh  
13 January 2003



**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**